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April 14, 2025

## **VIA ECF**

Honorable José R. Almonte, U.S.M.J. United States District Court District of New Jersey Frank Lautenberg Post Office & U.S. Courthouse 2 Federal Square Newark, New Jersey 07102

Re: Catalyst Pharmaceuticals, Inc., et al. v. Lupin Ltd., et al., C.A. No. 2:23-cv-01197-MEF-JRA –

Dear Judge Almonte:

Plaintiffs hereby provide their Reply letter brief in support of their motion to compel discovery from Lupin regarding (ECF No. 216).

\* \* \*

Plaintiffs seek an order compelling Lupin to produce all non-privileged documents in its

#### I. INTRODUCTION

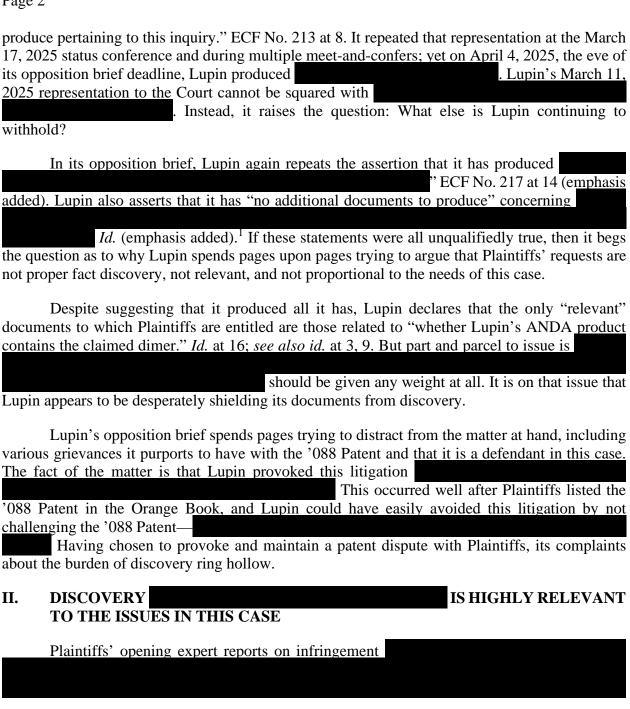
possession,	custody,	or	control	<u>pertaining</u>	to				
				. F	lainti	ffs also see	ek an orde	r compelling	Lupin to
make its Rul	le 30(b)(6)	witn	ess avai	lable to ansv	ver o	n topics tha	t Lupin alı	eady agreed	to make a
witness avai	lable on. Tl	he dis	scovery	Plaintiffs se	ek is	relevant and	d proportio	onal to the iss	ues in this
case.									
<u>Lu</u> pi	n originall	y pr	oduced	ANDA pro	oduct	samples			
th	nereafter re	fused	d to pro	duce				and now	maintains
objections					. ]	Then Lupin	, in turn,		
	Lupin see	eks to	o shield	fulsome dis	cover	v regarding	T .		

Lupin's opposition brief is replete with inconsistent, ever-evolving, and heavily qualified assertions. If Lupin had actually produced then this dispute would have been resolved long ago and Lupin's counsel could have offered an unqualified representation to that effect. Instead, Lupin has approached this dispute with a distinct lack of candor.

As one stark example, in the parties' March 11, 2025 joint discovery dispute letter, Lupin asserted that "Lupin does not have any other documents" to

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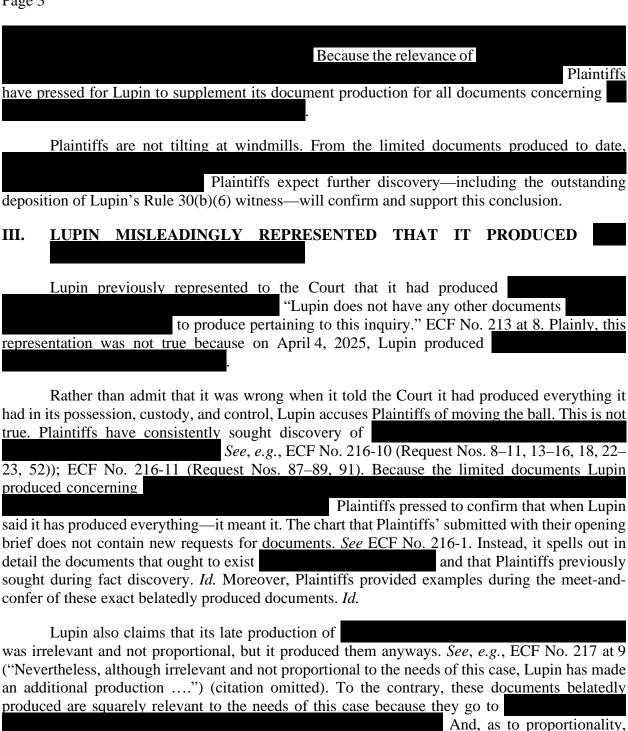
<sup>&</sup>lt;sup>1</sup> Lupin's approach throughout this discovery dispute (and throughout this case) of offering cryptic, ever-evolving responses has obstructed the swift resolution of disputes. *See*, *e.g.*, ECF No. 216 at 10 n.8. Plaintiffs have frustratingly chased Lupin—for over two months—for an answer to whether there are outstanding documents and even now are trying to parse Lupin's wordsmithing.

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Lupin's most recent production

some undue burden on Lupin does not merit a response.



Lupin's suggestion that this imposed

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It appears that Lupin's representations to the Court and to Plaintiffs hinge upon its own selective definition of Lupin considers "relevant." ECF No. at 16. This is precisely the type of discovery abuse that the 2015 Amendments to Rule 34 are intended to prevent. See Fed. R. Civ. P. 34, Advisory Committee Notes to 2015 Amendment, Subd. (b)(2)(c) (noting that a party must state if anything is being withheld on a basis of an objection to "alert other parties to the fact that documents have been withheld and thereby facilitate an informed discussion of the objection."). Here, Lupin does not appear to accept that documents relating to are "relevant" and, therefore, withheld them. See also ECF No. 217 at 3, 9. Lupin's resistance to addressing Plaintiffs' discovery dispute head-on has extended this dispute for months and there is still no clarity on what discovery remains outstanding.

#### IV. LUPIN'S DISCOVERY OBJECTIONS ARE UNAVAILING

A. Lupin overstates the significance of certain amendments to Rule 26 and ignores the Rule's ongoing duty to supplement.

In opposing Plaintiffs' motion to compel, Lupin argues that Plaintiffs' requests for discovery exceed the scope of discovery under Rule 26. Lupin's argument is largely captured in this statement:

The December 1, 2010 amendments to Fed. R. Civ. P. 26(b)(4)(B) and (C) fundamentally changed the nature and scope of required discovery pertaining to experts and the 2015 amendments to Fed. R. Civ. P. 26(b)(1) fundamentally changed the scope of discovery by adding the requirement that discovery be proportional to the needs of the case.

ECF No. 217 at 12. Lupin's argument implies that Plaintiffs' requests are inconsistent with these amendments that have been in effect for 10–15 years. This is incorrect. Lupin also hopes that these amendments distinguish Plaintiffs' caselaw, strengthen Lupin's privilege objections, and bolster its proportionality argument—but they do not. And, all the while, Lupin says nothing of its ongoing obligation to supplement its discovery responses as required *under the same Rule*. Lupin's inflated reliance on these amendments fails for at least the following three reasons.

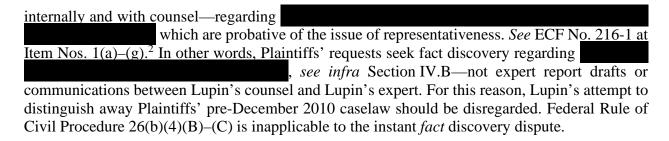
First, neither Rule 26(b)(4)(B)–(C) nor the December 2010 Amendments thereto—relating to the protection of expert report drafts and communications with a party's attorney and its expert—have any bearing on the instant dispute. Plaintiffs are not seeking any expert report drafts, communications between Lupin's counsel and Lupin's expert, or Lupin's communications regarding

Rather, Plaintiffs are seeking information about

See ECF No. 216 at 5–6 n.5. Plaintiffs also seek Lupin's communications—both

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Second, Lupin overstates the significance of the December 2015 Amendment to Rule 26(b)(1) regarding the scope of permissible discovery in a case. While the 2015 Amendment added language regarding proportionality, discovery has long been subject to limits on burden. For example, the Advisory Committee Notes for the 2015 Amendment indicate that "[r]estoring the proportionality calculation to Rule 26(b)(1) does not change the existing responsibilities of the court and the parties to consider proportionality, and the change does not place on the party seeking discovery the burden of addressing all proportionality considerations." Fed. R. Civ. P. 26, Advisory Committee Notes to 2015 Amendment, Subd. (b)(1).In fact, "[t]he considerations that bear on proportionality [we]re moved from...Rule 26(b)(2)(C)(iii), slightly rearranged and with one addition." Id. (further noting that "[m]ost of what now appears in Rule 26(b)(2)(C)(iii) was first adopted in 1983"). For this reason, Lupin's attempt to dismiss Plaintiffs' pre-December 2015 caselaw should be disregarded. See also Walls v. City of New York, 502 F. Supp. 3d 686, 691 n.3 (E.D.N.Y. 2020) ("Contrary to Defendants' argument, the 2015 Amendments to Rule 26(b) did not represent a fundamental change in the existing scope of discovery such that cases pre-dating 2015 would be inapposite.").

**Third**, Lupin selectively delves into the amendment history of Rule 26 but nowhere acknowledges in its opposition brief its own duty to supplement, which is imposed by that same Rule. Lupin was required under Rule 26, Subsection (e)(1)(A) to supplement its discovery responses:

(1) *In General*. A party who has made a disclosure under Rule 26(a) —or who has responded to an interrogatory, request for production, or request for admission—must supplement or correct its disclosure or response:

<sup>2</sup> To the extent Lupin asserts that these requested communications are privileged, as explained previously, Lupin has waived privilege on all communications on the same subject.

See ECF No. 216 at 7-8. Partial waivers are not permissible if it disadvantages Plaintiffs by allowing Lupin to present a one-sided story to the Court. *Id.* At a minimum, any communications or documents that Lupin deems privileged should be disclosed on a log so that Plaintiffs may investigate Lupin's claim and so the Court may review the documents in camera. See infra at § IV.D.

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(A) in a timely manner if the party learns that in some material respect the disclosure or response is incomplete or incorrect, and if the additional or corrective information has not otherwise been made known to the other parties during the discovery process or in writing....

Fed. R. Civ. P. 26(e)(1)(A). Here,

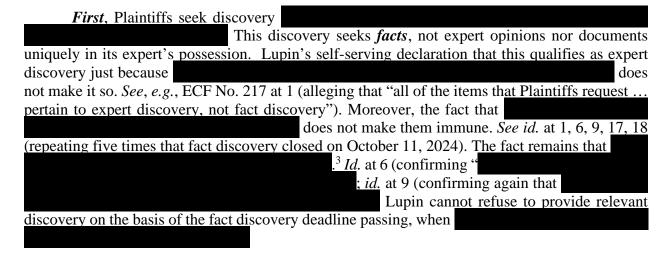
Lupin had a duty to supplement its document production

But Lupin made no effort to supplement its discovery responses or even notify Plaintiffs

Lupin violated Rule 26 by failing to comply with its duty to supplement.

## B. Lupin mislabels the discovery sought as "expert" discovery.

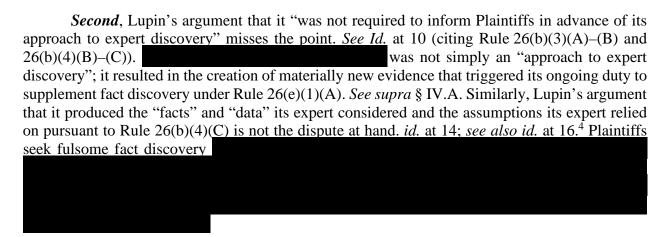
Lupin claims that everything Plaintiffs seek to compel constitutes expert discovery. This is incorrect. But by mislabeling the requested discovery as "expert" discovery, Lupin hopes to (1) capitalize on certain Federal Rules of Civil Procedure that provide protections for things such as expert report drafts and communications between a party's attorney and its expert, *see supra* § IV.A, and (2) argue Plaintiffs failed to comply with the Court's Order requiring a chart that "identifies the specific discovery items and information Plaintiffs contend should have been disclosed during fact discovery." *See infra* § IV.B (third point below); ECF No. 215. Lupin's approach fails for at least the following three reasons.



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Third, Lupin's allegation that Plaintiffs' chart, see ECF No. 216-1, failed to comply with the Court's order requiring an identification of "the specific discovery items and information Plaintiffs contend should have been disclosed during fact discovery," see ECF No. 215, is misguided. As a threshold matter, Lupin's interpretation of the Court's Text Order grips onto the phrase "during fact discovery," and notes that fact discovery closed on October 11, 2024, and flippantly states that true compliance therefore "would have been [an] entirely blank" chart. ECF No. 217 at 9. Lupin's parsing of the Order's words in this manner is improper. Factual evidence is not transformed into expert evidence because it is newly made after the close of fact discovery. To permit Lupin after the cutoff while simultaneously precluding an opportunity for fulsome discovery would encourage strategic delay and gamesmanship by parties seeking to create and rely upon evidence that cannot be tested or subject to discovery.

# C. Lupin's proportionality objection is nonsensical given its representation that there is nothing left to produce.

Lupin's proportionality argument fails for at least the following three reasons.

*First*, Lupin's proportionality argument is illogical. Lupin openly declared that it "has nothing more to produce beyond what it has already produced." ECF No. 217 at 17; *see also id.* at

<sup>&</sup>lt;sup>4</sup> Relatedly, Lupin attempts to distinguish *Supernus Pharmaceuticals, Inc. v. Twi Pharmaceuticals, Inc.* because it "involved [an] assertion of privilege over excipient selection that pertained to fact discovery, not expert discovery." *Id.* at 11 n.2 (citing *Supernus Pharms., Inc. v. Twi Pharms., Inc.*, 265 F. Supp. 3d 490, 516 n.11 (D.N.J. 2017)). Because Plaintiffs seek fact discovery, Lupin's attempted distinction is inapposite.

<sup>&</sup>lt;sup>5</sup> This is not the only instance in which Lupin attempts to spin a Court order. For example, Lupin complains that Plaintiffs refused to amend their infringement contentions, but makes no mention that the Court ordered that it was not necessary given the pending expert discovery. *See* ECF No. 174; ECF No. 217 at 10.

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14 ("With respect to Plaintiffs' request for documents relating , Lupin has no additional documents to produce."); *id.* ("with respect to Plaintiffs' requests in Item Nos. 1(a)-(g) of their chart (ECF No. 216-1), Lupin does not have any written internal communications concerning any of those items"). But if there is nothing left to produce, then why does Lupin waste the Court's time arguing about proportionality? *See*, *e.g.*, *Id.* at 2.

**Second**, if Lupin has nothing more to produce, as it repeatedly states, there would be no reason to object on the basis of proportionality. Instead, it begs the question, what is Lupin withholding? For example, Lupin's qualified statements that it has already produced documents "that are in any way *proportional* to the needs of this case" suggest that it has not produced those documents or communications it unilaterally deems as not proportional to the needs of this case. *Id.* at 2–3 (emphasis added); *see also id.* at 16 ("Lupin ... has produced all the information that is *proportional* to the needs of the case.") (emphasis added). Given that Lupin apparently considered documents regarding

to be "irrelevant and *not proportional*" and withheld them until April 4, 2025, it strongly suggests there may well be outstanding documents that Lupin is still unilaterally withholding. *Id.* at 9 (emphasis added); *see supra* § III.

**Third**, the proportionality inquiry takes into account the burden on the producing party. Fed. R. Civ. P. 26(b)(1) ("whether the burden or expense of the proposed discovery outweighs its likely benefit"). Lupin has objected on proportionality grounds, but it has made no showing of any burden whatsoever. Nor has it provided a proper and fulsome analysis of all proportionality factors. Hence, to the extent Lupin is withholding documents and communications on proportionality grounds, it has not made a proper showing that there is a lack of proportionality.<sup>6</sup>

## D. Lupin should be compelled to provide a privilege log for any withheld documents and communications.

Lupin should be compelled, at a minimum, to provide a privilege log for any withheld documents and communications regarding the Litigation Batch for the following reasons.

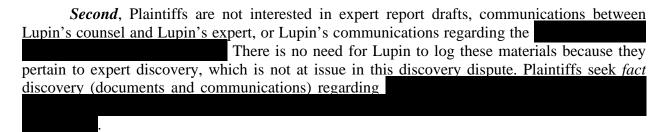
*First*, as previously referenced, Lupin has plainly asserted it "has nothing more to produce beyond what it has already produced." ECF No. 217 at 17. Plaintiffs fail to understand why Lupin has burdened the Court with an opposition argument against updating its privilege log if there truly

<sup>6</sup> Lupin claims that "Plaintiffs ma[de] no attempt in their letter brief to demonstrate a 'substantial need' for the protected discovery they request, as required by Fed. R. Civ. P. 26(b)(3)(A)(ii)." ECF No. 217 at 17. To the contrary, Plaintiffs' opening letter brief explains in detail why the requested discovery is both highly relevant and proportional, not least because Plaintiffs cannot obtain discovery regarding

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is "nothing more to produce." The argument itself suggests Lupin is withholding documents and communications on the basis privilege.



Third, as set forth in Plaintiffs' opening letter brief, see ECF No. 216 at 7, Lupin waived any privilege or work product protection (to the extent such protections applied) over these materials when it chose to

Thus, if Lupin is withholding such fact discovery (documents and communications) regarding on the basis of privilege, the Court should compel production of these materials or at least compel Lupin to identify them on a privilege log so Plaintiffs have the opportunity to challenge those privilege claims.

Fourth, the fact remains that courts in this same jurisdiction have sanctioned ANDA defendants under similar circumstances. See, e.g., Medeva Pharma Suisse A.G. v. Roxane Lab'ys, Inc., No. 07-5165-FLW, 2011 WL 310697, at \*19 (D.N.J. Jan. 28, 2011) (awarding attorney's fees, costs, and plaintiffs' reasonable expert fees for In refusing to provide a privilege log, Lupin has improperly denied Plaintiffs the opportunity to challenge any privilege claims that Lupin asserts over documents and communications

See Medeva, 2011 WL 310697, at \*18 ("if Roxane intended to withhold information regarding the existence of the Concealed Lot based on the work product doctrine, it had an obligation to specifically notify Medeva that it was doing so by including an entry in its privilege log regarding same").

*Fifth*, Lupin fails to distinguish *Medeva*. Lupin posits that *Medeva* was argued under "old rules" in place "before the December 1, 2010 amendments to Fed. R. Civ. P. 26(b)(4)(B) and (C) which created a clear dividing line that recognized the privileged nature of drafts and communications pertaining to expert discovery." ECF No. 217 at 10–11 (citation omitted). This is irrelevant. Rule 26(b)(4)(B) and (C) pertain to expert report drafts and communications between a party's attorney and its expert—Plaintiffs seek neither. Plaintiffs seek *fact* discovery about the Litigation Batch itself. *See supra* § IV.A.

Lupin further claims the ESI Order entered in this case absolves it of any obligation to provide a privilege log, whereas *Medeva* did not involve such an ESI Order. ECF No. 217 at 11;

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id. at 11 n.2. This argument likewise fails. The ESI Order merely identifies certain "[d]ocuments or ESI presumptively not to be logged on a privilege log ...," such as attorney work-product regarding this action. ECF. No. 57, ¶ 3(d)(ii) (emphasis added). However,

—is not exempt from privilege logging under the ESI Order. If these documents are not compelled outright, Lupin should, at a minimum, be required to provide a privilege log listing these documents that concern

Nor is *Medeva* distinguishable because Medeva tested the "Concealed Lot" whereas Plaintiffs did not. ECF No. 217 at 11; *id.* at 11 n.2.

The

requested discovery is no less relevant because

## E. Lupin's accusation that Plaintiffs did not seek an extension ignores the realities of the expert discovery timeline.

Lupin criticizes Plaintiffs for not delaying the expert discovery schedule and asserts that Plaintiffs should have sought an extension to the reply expert report deadline if Plaintiffs "truly felt they needed additional discovery." *See* ECF No. at 15. Lupin's argument is of no moment. Plaintiffs' expert, Dr. Blair, has already opined

Additional facts from

Lupin may further support Dr. Blair's opinion, in which case his report can be supplemented to incorporate the new discovery. Contrary to Lupin's suggestion, there is no requirement that Plaintiff call for a halt to expert reports to first resolve a discovery issue. Moreover, expert discovery is continuing to June 6, 2025, and Lupin's delay tactics should not be to their advantage.

### V. LUPIN'S REFUSAL TO MAKE ITS RULE 30(B)(6) WITNESS AVAILABLE

Lupin's refusal to make a Rule 30(b)(6) witness available to is untenable. Lupin designated Dr. Pritesh Upadhyay to speak on a number of topics on which is a central, relevant issue. Dr. Upadhyay's Topics include:

**Topic 7:** "Any actions and analyses Lupin has taken, or has directed any others to take, to determine whether Defendants' ANDA

<sup>7</sup> Notably, the defendant in *Medeva* similarly "argue[d] that it was not obligated to log the existence of the Concealed Lot or any documents concerning same on its privilege log because the Concealed Lot was created after the Complaint in this matter was filed and there is no rule requiring an ongoing privilege log." *Medeva*, 2011 WL 310697 at \*12. The court *still* sanctioned the defendant.

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Product and/or the amifampridine phosphate used in Defendants' ANDA Product does or does not contain any dimers of amifampridine phosphate;"

**Topic 15:** "The factual basis for Lupin's assertions that Defendants' ANDA Product or its use will not infringe (including direct, joint, indirect, literal, or under the doctrine of equivalents) each asserted claim of the Asserted Patents;" and

**Topic 16:** "The facts and circumstances relating to the testing conducted relating to the detection of the claimed dimer impurity in the API or ANDA Product, and the comparisons of Defendants' ANDA Product to FIRDAPSE® or to the Asserted Patents conducted by or on behalf of Lupin, including any attempts to copy or design around FIRDAPSE® or the Asserted Patents."

See Ex. 14 (Sept. 16, 2024 Letter from A. Lange).

is squarely at issue in each of Dr. Upadhyay's designated topics and the topics would be rendered largely meaningless if he cannot speak to
For example, Topic 7 relates to Lupin's actions and analysis to determine non-infringement
of its ANDA Product.  Plaintiffs need the opportunity to investigate
The discovery to date indicates that it
is not. Topic 15—the factual basis for Lupin's assertions of non-infringement—likewise implicate
Topic 16—the facts
and circumstances relating to the testing conducted relating to the detection of the claimed dimer—also squarely implicates
Lupin asserts that Plaintiffs delayed Dr. Upadhyay's deposition with "no legitimate justification," but that is manifestly incorrect, as
deposition topics. ECF No. 217 at 18. Lupin's assertion that Dr. Upadhyay had been "prepared to
provide testimony on the full scope of the Rule 30(b)(6) topics on which he was designated" is
also incorrect because Lupin refused to prepare him to testify on
which are fact discovery issues. <sup>8</sup> <i>Id.</i> at 19.

<sup>&</sup>lt;sup>8</sup> Lupin relies on the statement from *Campos v. County of Orange* that "a Rule 30(b)(6) deposition would not be the appropriate vehicle to obtain expert discovery," ECF No. at 19 (quoting *Campos v. County of Orange*, No. 23-72-WLH-JDE, 2024 WL 4799880, \*3 (C.D. Cal. Sept. 13, 2024) (citations omitted)), but Plaintiffs are not attempting to use Dr. Upadhyay's Rule 30(b)(6)

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Plaintiffs remain willing to conduct Dr. Upadhyay's deposition remotely provided that Lupin produces adequate discovery and further adequately prepares him to be deposed regarding the same. If Lupin continues to refuse to make Dr. Upadhyay, a Rule 30(b)(6) witness, available to testify on the topics for which he was designated, which also then Lupin should be precluded from offering any evidence from a Lupin witness.

#### VI. CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request an order from the Court compelling Lupin to:

- 1. Produce all documents and communications fall within the following categories:
  - a. Documents concerning
  - b. Documents concerning; and
  - c. Internal communications concerning
- 2. Produce all the requested discovery that fall within the categories listed in Item 1 that Lupin contends is privileged; or, in the alternative, identify any allegedly privileged documents and communications on a privilege log and provide them to the Court for *in camera* review.
- 3. Make Dr. Upadhyay available for his noticed Rule 30(b)(6) deposition and prepare him to be deposed regarding the full scope of his designated topics, which

deposition to acquire expert discovery. Moreover, in *Campos*, the plaintiff tried to compel a further Rule 30(b)(6) deposition after the fact discovery deadline. *Campos*, 2024 WL 4799880 at \*2–\*3. But here, Lupin has prevented Plaintiffs from taking the Rule 30(b)(6) deposition of Dr. Upadhyay for months because of its egregious discovery deficiencies and refusal to prepare Dr. Upadhyay to testify

<sup>&</sup>lt;sup>9</sup> Lupin goes on at length (at 7, 18-19) that Dr. Upadhyay was in Chicago for his originally scheduled deposition, but it was Lupin that insisted on the deposition taking place in person in Chicago because the witness was planning to be there for that entire week. *See* Ex. 13 at 1 (Jan. 22, 2025 E-mail from A. Lange). And, significantly, Lupin rejected the possibility of a second deposition of Dr. Upadhyay. Out of consideration for not having to inconvenience Dr. Upadhyay with two depositions or having to move the Court to compel Lupin to produce him twice, Plaintiffs sensibly adjourned the deposition.

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Respectfully submitted,

s/ Charles H. Chevalier Charles H. Chevalier

Attachments

cc: Counsel of Record (via e-mail)